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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
JUL 31 2007
U.S.D.C. S.D. N.Y.
CASHIERS

IN RE: FOSAMAX PRODUCTS LIABILITY
LITIGATION

MDL No. 1:06-md-1789- JFK

LELA CALLAWAY,
Plaintiff,

Case No. _____

v.

CIVIL COMPLAINT

MERCK & CO., INC. (hereinafter "Merck"), a
New Jersey Corporation

JURY TRIAL DEMANDED

Defendant.

LELA CALLAWAY, Plaintiff, by and through her undersigned counsel, sue
Defendant Merck & Co., Inc. and allege as follows:

I. PARTIES

1. Plaintiff is a resident of the State of Oklahoma, and Defendant, Merck, is
incorporated and has its primary place of business in the State of New Jersey.

2. Plaintiff, LELA CALLAWAY, was born May 1, 1952, and is a resident of
Medford, Grant County, Oklahoma. (Unless otherwise specified herein, the term "Plaintiff" as

1 used in the singular refers to Plaintiff, LELA CALLAWAY.) After taking FOSAMAX for an
2 extended period of time, Plaintiff was diagnosed with serious and permanent injuries.

3 3. Defendant, Merck, is a corporation organized and existing under the laws of the
4 State of New Jersey, with its principal place of business in New Jersey. The Defendant's
5 principal office is located at One Merck Drive, Whitehouse Station, New Jersey.
6

7 4. Defendant, Merck, was at all relevant times authorized to conduct business in the
8 State of Oklahoma.

9 5. Defendant has regularly transacted business in the State of Oklahoma and
10 continues to do so.

11 6. At all relevant times, Defendant, Merck, through its agents, servants, employees,
12 and apparent agents, was the designer, manufacturer, marketer, distributor, and seller of
13 FOSAMAX, a bisphosphonate drug used primarily to mitigate or reverse the effects of
14 osteoporosis, osteopenia, and Paget's Disease.
15

16 7. Defendant, Merck, either directly or through its agents, apparent agents, servants,
17 or employees, at all relevant times, sold and distributed FOSAMAX in the State of Oklahoma.

18 8. Defendant encouraged the use of this drug in improper customers, misrepresented
19 the safety and effectiveness of this drug, and concealed or understated its dangerous side effects
20 in Oklahoma. The Defendant aggressively marketed this drug directly to the consuming public
21 through the use of various marketing mediums including, but not limited to, print and television
22 advertisements in Oklahoma.
23

24 9. Based on information and belief, Sales Representatives called physicians on
25 numerous occasions at which times they presented fraudulent information regarding the safety
26 and efficacy of FOSAMAX and its harmful side effects, and/or fraudulently suppressed material
27 information regarding the safety and efficacy of FOSAMAX and its harmful side effects, and/or
28

1 placed FOSAMAX in the stream of commerce by providing Plaintiff's physician(s) samples of
2 the drug FOSAMAX.

3 10. At all times material hereto, Merck advertised, marketed, and/or produced
4 FOSAMAX to Plaintiff utilizing information known to fraudulently represent the safety and
5 efficacy of FOSAMAX, and said Defendant failed to warn of the known dangers and adverse
6 events associated with the use of the drug FOSAMAX.
7

8 11. At all times relevant hereto, the Defendant actually knew of the defective nature of
9 its product as herein set forth yet continued to design, manufacture, market, distribute, and sell the
10 product in Grant County, Oklahoma.

11 12. Defendant derives substantial revenue from pharmaceutical products used or
12 consumed in the State of Oklahoma.

13 13. Defendant expected, or should have expected, that its business activities could or
14 would have consequences within the State of Oklahoma.
15

16 14. Defendant placed FOSAMAX into the stream of worldwide commerce and
17 interstate commerce in the United States. They did so without adequate testing and with no
18 warning that the drug carried with it a risk of causing osteonecrosis or osteomyelitis of the jaw.

19 15. Plaintiff needs continued medical monitoring to treat serious and permanent
20 injuries which have already manifested.
21

22 II. JURISDICTION AND VENUE

23 16. This court has jurisdiction pursuant to 28 U.S.C. §§1332, as complete diversity
24 exists between Plaintiff and Defendant.

25 17. Plaintiff is a resident of the state of Oklahoma.
26

27 18. Defendant, Merck & Co., Inc., is incorporated and has its primary place of
28

1 business in the State of New Jersey. The amount in controversy, exclusive of interests and costs,
2 exceeds \$75,000.00.

3
4 19. Venue is proper within this district and division pursuant to agreement of the
5 parties.

6
7 **III. FACTUAL BACKGROUND**

8 20. Merck, either directly or through its agents, apparent agents, servants, or
9 employees, designed, manufactured, marketed, advertised, distributed, and sold FOSAMAX for
10 the treatment of osteoporosis, Paget's Disease, and other uses.

11
12 21. As a result of the defective nature of FOSAMAX, persons who were prescribed
13 and ingested FOSAMAX, including Plaintiff, LELA CALLAWAY, have suffered and may
14 continue to suffer severe and permanent personal injuries, including osteonecrosis and
15 osteomyelitis.

16 22. Merck concealed and continues to conceal its knowledge of FOSAMAX's
17 unreasonably dangerous risks from Plaintiff, LELA CALLAWAY, other consumers, and the
18 medical community.

19
20 23. Merck failed to conduct adequate and sufficient post-marketing surveillance of
21 FOSAMAX after it began marketing, advertising, distributing, and selling the drug.

22 24. As a result of Defendant's actions and inaction, Plaintiff, LELA CALLAWAY,
23 was injured due to her ingestion of FOSAMAX, which has caused and will continue to cause
24 Plaintiff various injuries and damages. Plaintiff accordingly seeks compensatory damages, as
25 well as other damages.

26
27 25. At all relevant times, Merck was responsible for, or involved in, designing,
28 manufacturing, marketing, advertising, distributing, and selling FOSAMAX.

1 26. In September 1995, the United States Food and Drug Administration ("FDA")
2 approved Merck's compound alendronate for various uses including the treatment of osteoporosis
3 and Paget's disease. Defendant, Merck, markets alendronate under the name FOSAMAX.

4 27. FOSAMAX falls within a class of drugs known as bisphosphonates.
5 Bisphosphonates are used for treating bone conditions such as osteoporosis and Paget's disease.
6 Other drugs within this class, such as Aredia and Zometa, are used as chemotherapy and as
7 adjunct chemotherapy but are not indicated for use in non-cancerous conditions such as
8 osteoporosis.
9

10 28. There are two classes of bisphosphonates: the N-containing (nitrogenous) and
11 nonN-containing (non-nitrogenous) bisphosphonates. The nitrogenous bisphosphonates include
12 the following: pamidronate (Aredia), ibandronate (Bondronat), and alendronate (FOSAMAX).
13 The non-nitrogenous bisphosphonates include the following: etridonate (Didronel), clodronate
14 (Bonefos and Loron), and tiludronate (Skelid). Alendronate contains a nitrogen atom. The
15 Physicians Desk Reference ("PDR") for FOSAMAX confirms that the molecule contains a
16 nitrogen atom.
17

18 29. Throughout the 1990s and 2000s, medical articles and studies appeared reporting
19 the frequent and common occurrence of osteonecrosis of the jaw within the nitrogenous
20 bisphosphonates used for chemotherapy. As with its reported and acknowledged side effects
21 concerning irritation, erosion, and inflammation of the upper gastrointestinal tract, Merck knew or
22 should have known that FOSAMAX, as a nitrogenous bisphosphonate, shared a similar adverse
23 event profile to the other drugs within this specific subclass of bisphosphonates (i.e., those
24 containing nitrogen).
25

26 30. Merck knew, and or should have known, that bisphosphonates, including
27 FOSAMAX, inhibit endothelial cell function. Similarly, Merck knew, or should have known,
28

1 that bisphosphonates also inhibit vascularization of the affected area and induce ischemic changes
2 specific to patients' mandibles (lower jaws) and maxillae (upper jaws) and that these ischemic
3 changes appear to be cumulative in nature.

4
5 31. Merck also knew, or should have known, that these factors combine to create a
6 compromised vascular supply in the affected area. As a result, a minor injury or disease can turn
7 into a non-healing wound. That, in turn, can progress to widespread necrosis (bone death) and
8 osteomyelitis (infection of the bone).

9
10 32. Dentists are now being advised by dental associations to refrain from using any
11 invasive procedure (such as drilling a cavity) for any patient on FOSAMAX.

12
13 33. Once the osteonecrosis begins and becomes symptomatic, it is very difficult to
14 treat and typically is not reversible.

15
16 34. Shortly after Merck began selling FOSAMAX, reports of osteonecrosis of the jaw
17 and other dental complications among users began surfacing, indicating that FOSAMAX shared
18 the class effects of the other nitrogenous bisphosphonates. Despite this knowledge, Merck failed
19 to implement further study regarding the risk of osteonecrosis of the jaw relative to FOSAMAX.
20 Rather than evaluating and verifying the safety of FOSAMAX with respect to osteonecrosis of
21 the jaw, Defendant proposed further uses of FOSAMAX, such as FOSAMAX-D, and sought to
22 extend the exclusivity period of FOSAMAX through 2018.

23
24 35. Osteonecrosis of the jaw is a serious medical event and can result in severe
25 disability and death.

26
27 36. Since FOSAMAX was released, the FDA has received a significant number of
28 reports of osteonecrosis of the jaw among users of FOSAMAX.

37. On August 25, 2004, the United States Food & Drug Administration ("FDA")
posted its ODS Postmarketing Safety Review on bisphosphonates - - specifically, pamidronate

1 (Aredia), zoledronic acid (Zometa), risedronate (Actonel), and alendronate (FOSAMAX).

2 38. As a result of the FDA Review, the FDA observed that the risk of osteonecrosis of
3 the jaw was not confined to bisphosphonates used for chemotherapy. The FDA's review
4 indicated that the osteonecrosis of the jaw was a class effect which specifically extended to the
5 oral bisphosphonate, FOSAMAX.
6

7 39. As a result, the FDA recommended and stated that the labeling for FOSAMAX
8 should be amended by Defendant, Merck, to specifically warn about the risk of osteonecrosis of
9 the jaw. Defendant, Merck, has refused to accede to the FDA's request and to this day still does
10 not warn of the risk of osteonecrosis of the jaw in its FOSAMAX labeling.
11

12 40. Rather than warn patients, and despite knowledge known by Defendant about
13 increased risk of osteonecrosis of the jaw in patients using FOSAMAX, Defendant continues to
14 defend FOSAMAX, mislead physicians and the public, and minimize unfavorable findings.

15 41. FOSAMAX is one of Merck's top selling drugs, averaging more than \$3 billion a
16 year in sales.

17 42. Consumers, including Plaintiff, LELA CALLAWAY, who has used FOSAMAX
18 for the treatment of osteoporosis, have several alternative, safer products available to treat the
19 conditions.
20

21 43. Defendant knew of the significant risk of dental and oral complications caused by
22 ingestion of FOSAMAX, but Defendant did not adequately and sufficiently warn consumers,
23 including Plaintiff, LELA CALLAWAY, or the medical community of such risks.

24 44. In an elaborate and sophisticated manner, Defendant aggressively marketed
25 FOSAMAX directly to consumers and medical professionals (including physicians and leading
26 medical scholars) in order to leverage pressure on third party payers, medical care organizations,
27 and large institutional buyers (e.g., hospitals) to include FOSAMAX on their formularies. Faced
28

1 with the increased demand for the drug by consumers and health care professionals that resulted
2 from Defendant's successful advertising and marketing blitz, third party payers were compelled
3 to add FOSAMAX to their formularies. Defendant's marketing campaign specifically targeted
4 third party payers, physicians, and consumers and was designed to convince them of both the
5 therapeutic and economic value of FOSAMAX.
6

7 45. As a direct result, Plaintiff, LELA CALLAWAY, was prescribed FOSAMAX and
8 has been permanently and severely injured, having suffered serious consequences from the
9 ingestion of FOSAMAX. Plaintiff, LELA CALLAWAY, requires and will in the future require
10 ongoing medical care and treatment.
11

12 46. Plaintiff, LELA CALLAWAY, has suffered from mental anguish from the
13 knowledge that Plaintiff will have life-long complications as a result of the injuries Plaintiff
14 sustained from the Plaintiff's use of FOSAMAX.
15

16 47. Plaintiff, LELA CALLAWAY, was prescribed and began taking FOSAMAX in
17 September of 2000.
18

19 48. Plaintiff used FOSAMAX as prescribed and in a foreseeable manner.
20

21 49. As a direct and proximate result of using FOSAMAX, Plaintiff suffered
22 development of serious and permanent injuries.
23

24 50. Plaintiff, as a direct and proximate result of using FOSAMAX, suffered severe
25 mental and physical pain and suffering and has sustained permanent injuries and emotional
26 distress.
27

28 51. Plaintiff used FOSAMAX which had been provided to her in a condition that was
substantially the same as the condition in which it was manufactured and sold.

52. Plaintiff would not have used FOSAMAX had Defendant properly disclosed the
risks associated with the drug.

1 53. Merck, through its affirmative misrepresentations and omissions, actively
2 concealed from Plaintiff and her physicians the true and significant risks associated with taking
3 FOSAMAX. The running of any applicable statute of limitations has been tolled by reason of
4 Merck's fraudulent concealment.

5
6 54. As a result of Defendant's actions, Plaintiff and her prescribing physicians were
7 unaware and could not have reasonably known or have learned through reasonable diligence that
8 Plaintiff had been exposed to the risks identified in this complaint and that those risks were the
9 direct and proximate result of Defendant's acts, omissions, and misrepresentations.

10 **IV. EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS**

11 55. The running of any statute of limitations has been tolled by reason of Defendant's
12 fraudulent concealment. Defendant, through its affirmative misrepresentation and omissions,
13 actively concealed from Plaintiff and her prescribing physician the true risks associated with
14 taking FOSAMAX.

15
16 56. As a result of Defendant's actions, Plaintiff and, upon information and belief, her
17 prescribing physician were unaware, and could not reasonably know or have learned through
18 reasonable diligence, that she had been exposed to the risks alleged herein and that those risks
19 were the direct and proximate result of Defendant's acts and omissions.

20
21 57. Furthermore, Defendant is estopped from relying on any statute of limitations
22 because of their fraudulent concealment of the true character, quality, and nature of FOSAMAX.
23 Defendant was under a duty to disclose the true character, quality, and nature of FOSAMAX
24 because this was non-public information over which the Defendant had and continues to have
25 exclusive control and because the Defendant knew that this information was not available to the
26 plaintiffs, medical providers, and/or to their facilities. In addition, the Defendant is estopped
27 from relying on any statute of limitations because of their intentional concealment of these
28

1 facts.

2 58. The Plaintiff had no knowledge that the Defendant was engaged in the wrongdoing
3 alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendant,
4 the Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the
5 economics of this fraud should be considered. The Defendant had the ability to and did spend
6 enormous amounts of money in furtherance of their purpose of marketing and promoting a
7 profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical
8 professionals could not have afforded and could not have possibly conducted studies to determine
9 the nature, extent, and identity of related health risks and were forced to rely on only the
10 Defendant's representations.
11

12 COUNTS

13 COUNT I: NEGLIGENCE

14 59 Plaintiff restates the allegations set forth above as if fully rewritten herein.

15 60. The Defendant owed Plaintiff, LELA CALLAWAY, and other consumers a duty
16 to exercise reasonable care when designing, manufacturing, marketing, advertising, distributing,
17 and selling FOSAMAX.
18

19 61. The Defendant failed to exercise due care under the circumstances and therefore
20 breached this duty by:
21

- 22 a. Failing to properly and thoroughly test FOSAMAX before releasing the drug
23 to market;
- 24 b. Failing to properly and thoroughly analyze the data resulting from the pre-
25 marketing tests of FOSAMAX.
- 26 c. Failing to conduct sufficient post-market testing and surveillance of
27 FOSAMAX;
28

- d. Designing, manufacturing, marketing, advertising, distributing, and selling FOSAMAX to consumers, including Plaintiff, without an adequate warning of the significant and dangerous risks of FOSAMAX and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
- e. Failing to exercise due care when advertising and promoting FOSAMAX; and
- f. Negligently continuing to manufacture, market, advertise, and distribute FOSAMAX after Defendant knew or should have known of its adverse effects.
- g. Defendant know, or should have known, that consumers, including Plaintiff, would suffer injuries as a result of Defendant's failure to exercise ordinary care.

62. As a direct and proximate consequence of Defendant's actions, negligence, omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and permanent injuries and will continue to suffer injury, harm, and economic loss.

63 Defendant's conduct as described above was committed with knowing, conscious, wanton, willful, and deliberate disregard for the value of human life and the rights and safety of consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish Defendant and deter Defendant from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II: STRICT LIABILITY

64. Plaintiff restates the allegations set forth above as if fully rewritten herein.

65. Merck manufactured, sold, distributed, marketed, and/or supplied FOSAMAX in a

1 defective and unreasonably dangerous condition to consumers, including Plaintiff, LELA
2 CALLAWAY. As such, Defendant had a duty to warn the using public, including Plaintiff, of the
3 health risks associated with using the product.

4 66. Merck designed, manufactured, sold, distributed, supplied, marketed, and/or
5 promoted FOSAMAX, which was expected to reach and did in fact reach consumers, including
6 Plaintiff, without substantial change in the condition in which it was manufactured and sold by
7 the Defendant.

8 67. Plaintiff used FOSAMAX as prescribed and in a manner normally intended,
9 recommended, promoted, and marketed by Defendant.

10 68. FOSAMAX failed to perform safely when used by ordinary consumers, including
11 Plaintiff, including when it was used as intended and in a reasonably foreseeable manner.

12 69. FOSAMAX was defective in its design and was unreasonably dangerous in that its
13 unforeseeable risks exceeded the benefits associated with its design or formulation.

14 70. FOSAMAX was defective in design or formation in that it posed a greater
15 likelihood of injury than other similar medications and was more dangerous than an ordinary
16 consumer could reasonably foresee or anticipate.

17 71. FOSAMAX was defective in its design and was unreasonably dangerous in that it
18 neither bore nor was packaged with nor accompanied by warning adequate to alert consumers,
19 including Plaintiff, of the risks described herein, including, but not limited to, the risk of
20 osteonecrosis of the jaw.

21 72. Although Defendant knew, or should have known, of the defective nature of
22 FOSAMAX, Merck continued to design, manufacture, market, and sell FOSAMAX so as to
23 maximize sales and profits at the expense of the public health and safety. By so acting, Merck
24 acted with conscious and deliberate disregard of the foreseeable harm caused by FOSAMAX.

1 73. Plaintiff could not, through the exercise of reasonable care, have discovered
2 FOSAMAX's defects or perceived the dangers posed by the drug. Plaintiff would not have used
3 FOSAMAX had the Defendant properly disclosed the risk associated with the drug.
4

5 74. As a direct and proximate consequence of Defendant's actions, negligence,
6 omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and
7 permanent injuries and will continue to suffer injury, harm, and economic loss.

8 75. Defendant's conduct as described above was committed with knowing, conscious,
9 wanton, willful, and deliberate disregard for the value of human life and the rights and safety of
10 consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish
11 Defendant and deter Defendant from similar conduct in the future.
12

13 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
14 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
15 the Court deems proper.

16 **COUNT III: BREACH OF EXPRESS WARRANTY**

17 76. Plaintiff restates the allegations set forth above as if fully rewritten herein.
18

19 77. Defendant expressly represented to Plaintiff, LELA CALLAWAY, and other
20 consumers and the medical community that FOSAMAX was safe and fit for its intended
21 purposes- that it was of merchantable quality, that it did not produce any dangerous side effects,
22 and that it was adequately tested.

23 78. FOSAMAX does not conform to Defendant's express representations because it is
24 not safe, has numerous side effects, and causes severe and permanent injuries.

25 79. At all relevant times, FOSAMAX did not perform as safely as an ordinary
26 consumer would expect when used as intended or in a reasonably foreseeable manner.
27

28 80. Plaintiff, LELA CALLAWAY, other consumers, and the medical community

1 relied upon Defendant's express warranties.

2 81. As a direct and proximate consequence of Defendant's actions, negligence,
3 omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and
4 permanent injuries and will continue to suffer injury, harm, and economic loss.

5 82. Defendant's conduct as described above was committed with knowing, conscious,
6 wanton, willful, and deliberate disregard for the value of human life and the rights and safety of
7 consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish
8 Defendant and deter Defendant from similar conduct in the future.

9 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
10 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
11 the Court deems proper.
12

13 **COUNT IV: BREACH OF IMPLIED WARRANTY**
14

15 83. Plaintiff restates the allegations set forth above as if fully rewritten herein.

16 84. Defendant manufactured, distributed, advertised, promoted, and sold FOSAMAX.

17 85. At all relevant times, Defendant knew of the use for which FOSAMAX was
18 intended and impliedly warranted the product to be of merchantable quality and safe and fit for
19 such use.

20 86. Merck was aware that consumers, including Plaintiff, LELA CALLAWAY, would
21 use FOSAMAX for treatment of osteoporosis and for other purposes.

22 87. Plaintiff and the medical community reasonably relied upon the judgment and
23 sensibility of Merck to sell FOSAMAX only if it was indeed of merchantable quality and safe and
24 fit for its intended use.

25 88. Defendant breached its implied warranty to consumers, including Plaintiff;
26 FOSAMAX was not of merchantable quality or safe and fit for its intended use.
27
28

1 89. Consumers, including Plaintiff, and the medical community reasonably relied upon
2 Defendant's implied warranty of FOSAMAX.

3 90. FOSAMAX reached consumers without substantial change in the condition in
4 which it was manufactured and sold by Defendant.

5 91. As a direct and proximate consequence of Defendant's actions, negligence,
6 omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and
7 permanent injuries and will continue to suffer injury, harm, and economic loss.

8 92. Defendant's conduct as described above was committed with knowing, conscious,
9 wanton, willful, and deliberate disregard for the value of human life and the rights and safety of
10 consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish
11 Defendant and deter it from similar conduct in the future.

12 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
13 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
14 the Court deems proper.

15 **COUNT V: FRAUDULENT MISREPRESENTATIONS**

16 93. Plaintiff restates the allegations set forth above as if fully rewritten herein.

17 94. Merck made fraudulent misrepresentations with respect to FOSAMAX in the
18 following particulars:

- 19 a. Defendant represented through its labeling, advertising, marketing, materials,
20 detail persons, seminar presentations, publications, notice letters, and
21 regulatory submissions that FOSAMAX had been tested and found to be safe
22 and effective for the prevention and treatment of osteoporosis; and
23 b. Defendant represented that FOSAMAX was safer than other alternative
24 medications.

1 95. Defendant knew that their representations were false, yet they willfully, wantonly,
2 and recklessly disregarded their obligation to provide truthful representations regarding the safety
3 and risk of FOSAMAX to consumers, including Plaintiff, and the medical community.

4 96. The representations were made by Defendant with the intent that doctors and
5 patients, including Plaintiff, rely upon them.

6 97. Defendant's representations were made with the intent of defrauding and
7 deceiving Plaintiff, other consumers, and the medical community to induce and encourage the
8 sale of FOSAMAX.

9 98. Plaintiff's doctors and others relied upon the representations.

10 99. Defendant's fraudulent representations evinced its callous, reckless, willful, and
11 depraved indifference to the health, safety, and welfare of consumers, including Plaintiff.

12 100. As a direct and proximate consequence of Defendant's actions, negligence,
13 omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and
14 permanent injuries and will continue to suffer injury, harm, and economic loss.

15 101. Defendant's conduct as described above was committed with knowing, conscious,
16 wanton, willful, and deliberate disregard for the value of human life and the rights and safety of
17 consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish
18 Defendant and deter it from similar conduct in the future.

19 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
20 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
21 the Court deems proper.

22 **COUNT VI: FRAUDULENT CONCEALMENT**

23 102. Plaintiff restates the allegations set forth above as if fully rewritten herein.

24 103. Merck's fraudulently concealed information with respect to FOSAMAX in the
25
26
27
28

1 following particulars:

- 2 a. Merck represented through its labeling, advertising, marketing, materials, detail
3 persons, seminar presentations, publications, notice letters, and regulatory
4 submissions that FOSAMAX was safe and fraudulently withheld and concealed
5 information about the substantial risks of using FOSAMAX; and
6
7 b. Merck represented that FOSAMAX was safer than other alternative medications
8 and fraudulently concealed information which demonstrated that FOSAMAX was
9 not safer than alternatives available on the market.

10 104. Merck had sole access to material facts concerning the dangers and unreasonable
11 risks of FOSAMAX.

12 105. The concealment of information by Defendant about the risks of FOSAMAX was
13 intentional, and the representations made by Defendant were known by Defendant to be false.

14 106. The concealment of information and the misrepresentations about FOSAMAX
15 were made by Defendant with the intent that doctors and patients, including Plaintiff, rely upon
16 them.
17

18 107. Plaintiff's doctors and others relied upon the representations and were unaware of
19 the substantial dental and oral risks of FOSAMAX which Defendant concealed from Plaintiff's
20 doctors and Plaintiff.
21

22 108. As a direct and proximate consequence of Defendant's actions, negligence,
23 omissions, and misrepresentations, Plaintiff, LELA CALLAWAY, has sustained serious and
24 permanent injuries and will continue to suffer injury, harm, and economic loss.

25 109. Defendant's conduct as described above was committed with knowing, conscious,
26 wanton, willful, and deliberate disregard for the value of human life and the rights and safety of
27 consumers such as Plaintiff, thereby entitling Plaintiff to punitive damages so as to punish
28

1 Defendant and deter it from similar conduct in the future.

2 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive
3 damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court
4 deems proper.

5
6 **COUNT VII: PUNITIVE DAMAGES**

7 110. Plaintiff restates the allegations set forth above as if fully rewritten herein.

8 111. Merck has repeatedly engaged in a pattern of conduct of deliberately avoiding
9 FDA recommendations relating to public hazards about which the public should be warned.

10 112. For instance, in March 2000, Merck completed a study called VIGOR (VIOXX
11 Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, VIOXX. The
12 VIGOR study showed that VIOXX patients had more than double the rate of serious
13 cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug.
14 The study was published in the *New England Journal of Medicine*.

15
16 113. In September 2001, the FDA warned Merck to stop misleading doctors about
17 VIOXX's effect on the cardiovascular system. Defendant, Merck, was admonished to stop
18 minimizing the risks of the drug in its marketing. Despite that, Defendant, Merck, refused to
19 adequately warn physicians and patients about the risk of heart attacks while taking VIOXX.

20
21 114. On August 25, 2004, a representative from the FDA presented results of a database
22 analysis of 1.4 million patients. The analysis demonstrated that VIOXX users were more likely to
23 suffer a heart attack or sudden cardiac death than those taking older non-steroidal drugs. The
24 FDA representatives concluded that VIOXX was linked to more than 27,000 heart attacks or
25 sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

26 115. On August 26, 2004, Merck released a press statement which refuted the FDA
27 analysis and restated Merck's support for the cardiovascular safety of VIOXX.
28

1 116. On September 30, 2004, Merck recalled VIOXX from the market after having to
2 halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The study was underway
3 to evaluate the use of VIOXX for recurrent colon polyps. The researchers found an alarming
4 number of cardiovascular events among the drug users in the APPROVe study.

5 117. At the same time, Merck was aware that the FDA, as of August 24, 2004, was
6 advising Merck to warn about the risk of osteonecrosis of the jaw for its FOSAMAX patients.
7 Because Merck knew that its blockbuster drug VIOXX was about to be pulled from the market,
8 placing more importance on the \$3 billion annual sales of FOSAMAX, Merck deliberately chose
9 to not amend its packaging of FOSAMAX to include the risk of osteonecrosis of the jaw, fearing
10 that such a warning would result in reduced revenues for its second largest income producer,
11 FOSAMAX.
12

13 118. Merck's acts were willful and malicious in that Merck's conduct was carried on
14 with a conscious disregard for the safety and rights of Plaintiffs. Defendant's unconscionable
15 conduct thereby warrants an assessment of exemplary and punitive damages against Merck in an
16 amount appropriate to punish Merck and deter similar conduct in the future.
17

18 119. Although Defendant knew or recklessly disregarded the fact that the subject
19 product causes debilitating and potentially lethal side effects, Defendant continued to market the
20 subject product to consumers, including Plaintiff, without disclosing these side effects.
21

22 120. Defendant knew of the subject product's defective nature, as set forth herein, but
23 continued to design, manufacture, market, and sell it so as to maximize sales and profits at the
24 expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent
25 disregard of the foreseeable harm caused by the subject product.

26 121. Defendant intentionally concealed or recklessly failed to disclose to the public,
27 including Plaintiff, the potentially life-threatening side effects of the subject product to ensure
28

1 their continued and increased sales. This intentional and/or reckless failure to disclose
2 information deprived Plaintiff of the information necessary for her to weigh the true risks of using
3 the subject product against the benefits.

4 122. Defendant's aforementioned conduct was committed with knowing, conscious,
5 and deliberate disregard for the rights and safety of consumers such as Plaintiff, thereby entitling
6 Plaintiff to punitive damages in an amount appropriate to punish Defendant and deter it from
7 similar conduct in the future.

8
9 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
10 punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as
11 the Court deems proper.

12
13 **COUNT IX**
14 **Products Liability - Failure to Warn**

15 123. The foregoing paragraphs of this Complaint are realleged and incorporated by
16 reference.

17 124. Defendant designed, tested, manufactured, marketed, sold and/or distributed
18 FOSAMAX. As such, it had a duty to warn the using public, including Plaintiff, of the health
19 risks associated with using the subject product.

20 125. The subject product was under the exclusive control of Defendant and was
21 unaccompanied by appropriate warnings regarding the health risks associated with its use,
22 including osteonecrosis of the jaw. The warnings given did not accurately reflect the risk,
23 incidence, symptoms, scope or severity of such injury to the consumer. The promotional activities
24 of Defendant further diluted or minimized the warnings given with the product.

25 126. The subject product was defective and unreasonably dangerous when it left the
26 possession of the Defendant in that it contained warnings insufficient to alert Plaintiff to the
27
28

1 dangerous risks and reactions associated with it, including, but not limited to osteonecrosis of the
2 jaw. Even though Defendant knew or should have known of the risks and reactions associated
3 with the subject product, it still failed to provide warnings that accurately reflected the signs,
4 symptoms, incidence, scope, or severity of these risks.

5
6 127. Plaintiff used the subject product for its intended purpose, i.e. for the prevention or
7 treatment of osteoporosis.

8 128. Plaintiff could not have discovered any defect in the subject product through the
9 exercise of reasonable care.

10 129. Defendant, as a manufacturer of pharmaceutical drugs, is held to the level of
11 knowledge of an expert in the field, and further, Defendant had knowledge of the dangerous risks
12 and side effects of the subject product.

13
14 130. Plaintiff did not have the same knowledge as Defendant and no adequate warning
15 was communicated to her.

16 131. Defendant had a continuing duty to warn consumers, including Plaintiff, of the
17 dangers associated with the subject product. By negligently and/or wantonly failing to adequately
18 warn of the dangers of use of the subject product, Defendant breached its duty.

19 132. Although Defendant knew of the defective nature of the subject product, they
20 continued to design, manufacture, market, and sell it without providing accurate, adequate, and
21 complete warnings concerning its use so as to maximize sales and profits at the expense of the
22 public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm
23 caused by the subject product.

24
25 133. As a direct and proximate result of the Defendant's failure to adequately warn or
26 other wrongdoing and actions of Defendant described herein, Plaintiff has sustained serious and
27 permanent injuries, and will continue to suffer injury, harm, and economic loss.
28

1 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
2 punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as
3 the Court deems proper.

4 WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and
5 punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as
6 the Court deems proper.
7

8
9 **PRAYER FOR RELIEF**

10 WHEREFORE, Plaintiffs pray for judgment against Defendant as follows:

- 11 1. General damages in an amount to be proven at the time of trial;
- 12 2. Special damages in an amount to be proven at the time of trial;
- 13 3. Exemplary and punitive damages in an amount to be proven at the time of trial
14 and sufficient to punish Defendant or to deter Defendant and others from
15 repeating the injurious conduct alleged herein;
- 16 4. Pre-judgment and post-judgment interest on the above general and special
17 damages;
- 18 5. For costs of this suit and attorney's fees;
- 19 6. All other relief to which Plaintiff may be entitled;
- 20 7. That the costs of this action be taxed to Defendant;
- 21 8. That Plaintiff be granted reasonable attorneys' fees and costs as provided by
22 law; and
- 23 9. For such other and further relief as the Court may deem just and proper.
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1 Dated: 7/30/07

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2
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DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all claims so triable in this action.

Dated: 7/3-107

REICH & BINSTOCK, LLP

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